Response to Office Action of August 25, 2005

REMARKS

In the final Office Action dated August 25, 2005, Claims 1-19 were pending. The Office Action objects to Claim 16 as having insufficient antecedent basis for the phrase "said stop," and rejects Claims 1-19 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 5,688,241 to Asbaghi.

On November 30, 2005, Applicant submitted a response to the Office Action proposing amendments and presenting remarks regarding the rejection of the claims as being unpatentable over Asbaghi. On December 15, 2005, an Advisory Action was mailed indicating the proposed amendments were not entered. Therefore, the amendments proposed in the preceding pages of this paper are directed to the state of the application as of the date of the final Office Action without regard to the amendments proposed on November 30, 2005.

In particular, an amendment herein to Claim 16 is made toward the antecedent basis of the phrase "said stop." Applicant submits that the antecedent basis of the phrase is now clearly established and respectfully requests further examination of Claim 16. Additionally, amendments herein to Claims 5, 7-11, 13, 15, and 17-19 attend to minor clarifications of those claims.

The specification of the present application describes a device having a sleeve that reaches a **permanently** locked position as a needle is withdrawn from a patient. In the locked position, the sleeve covers the tip of the needle and prevents the needle from being reused. The sleeve is shown in the fully extended and locked position in FIG. 6, wherein fingers 62 engage the undercut portion 114 thus permanently preventing the sleeve 22 from retracting and exposing the needle 28. If tampering with the fingers 62 were possible, their engagement with the undercut portion 114 could be released and the needle could be reused by pressing of the sleeve 22 back into the casing 30 and into the positions shown in FIGS. 4 and 5. However such tampering is not possible and the disposition of the sleeve in the **locked position of FIG. 6 is permanent because the fingers 62 are entirely covered by the casing 30**.

The Asbaghi reference discloses an inner cylinder 26 that extends from an outer cylinder 20 to reach a third extended safety position wherein flaps 52a are released providing a locking function. However, as shown in FIGS. 1 and 6c of Asbaghi, the flaps 52a are clearly exposed when the safety position is reached and are therefore susceptible to tampering. By merely

Response to Office Action of August 25, 2005

pressing the flaps 52a radially inward toward the central axis of the inner cylinder 26, a user of the Asbaghi device could effect the unlocking of the cylinder and could then return the cylinder to the positions shown in FIGS. 6a and 6b. That is, the locking function of the Asbaghi device is not permanent because the flaps 52a are not covered and are susceptible to being pressed.

The independent Claim 1 of the present application, as amended herein, requires that a sleeve has a "third position wherein said sleeve covers said entire needle and is locked in position ...," and that "said stop member automatically **permanently** locks said sleeve in said third position upon withdrawal of said needle from a patient." Therefore Claim 1 as amended, and Claims 2-11 that depend either directly or indirectly from Claim 1, are patentable over the Asbaghi reference for at least the reason that Asbaghi does not disclose and does not render obvious a stop member that **permanently** locks a sleeve.

The independent Claim 12 of the present application, as amended herein, requires that a sleeve, which is reciprocally movably associated with a hollow body, has a **flexible finger disposed within the hollow body** and that **the finger remains disposed within the hollow body** and locks the sleeve into a (third) position wherein the sleeve covers a needle. Therefore Claim 12, and Claims 13-19 that depend either directly or indirectly from claim 12, are patentable over the Asbaghi reference for at least the reason that Asbaghi does not disclose a covered locking mechanism, and particularly does not disclose and does not render obvious a flexible finger that remains disposed within a hollow body and locks a sleeve in a needle covering position.

The independent Claim 20 of the present application, newly presented herein, requires that a sleeve, which is reciprocally movably associated with a hollow body, includes **flexible fingers that are disposed within the hollow body**. According to claim 20, upon withdrawal of a needle from a patient, the sleeve moves automatically to a third position, wherein the sleeve covers the needle, and **at least one of the flexible fingers engages a stop surface disposed internally within the hollow body**. However, both the flaps 52a of FIG. 1 of the Asbaghi reference, and the surface they abut in tentatively locking the cylinder 26 are disposed along the exterior of the Asbaghi device when the device is locked. Therefore Claim 20 is patentable over the Asbaghi reference for at least the reason that Asbaghi does not disclose and does not render

Response to Office Action of August 25, 2005

obvious a flexible finger disposed within a hollow body engaging a stop surface disposed internally within the hollow body.

The independent Claim 21 of the present application, newly presented herein, requires that a sleeve, which is telescopically engaged with a hollow body, is capable of moving to a third position wherein the free end of a needle is covered by the sleeve. Claim 21 further requires that a flexible member disposed within the hollow body automatically and permanently locks the sleeve into the third position. As previously discussed, the Asbaghi reference does not disclose or render obvious a flexible member, which is disposed within a hollow body, that locks a sleeve to cover a needle. Furthermore, as previously discussed, Asbaghi does not disclose or render obvious a flexible member that permanently locks a sleeve to cover a needle.

In summary, the teachings of Asbaghi do not disclose or render obvious all of the features of any one of the independent Claims 1, 12, 20, and 21, each of which is either amended herein or is newly presented herein. The Applicant respectfully submits that these claims are each patentable over Asbaghi and over other references previously cited by the Examiner. Furthermore, Claims 2-11 and 13-19, which directly or indirectly depend from Claims 1 and 12, respectively, are patentable because the independent claims from which they depend are patentable. Therefore, the Applicant respectfully submits that each of the current Claims 1-21, as amended herein, is patentable over the Asbaghi reference and over all other references of which the Applicant is aware.

Response to Office Action of August 25, 2005

CONCLUSIONS

In view of the remarks presented above, Applicant submits that the present application is in condition for allowance. As such, the issuance of a Notice of Allowance is therefore respectfully requested. In order to expedite the examination of the present application, the Examiner is encouraged to contact the Applicant's undersigned attorney in order to resolve any remaining issues.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Brian D. MacDonald Registration No. 54,288

Customer No. 00826 ALSTON & BIRD LLP Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Charlotte Office (704) 444-1000 Fax Charlotte Office (704) 444-1111

"Express Mail" mailing label number EV 521116997 US Date of Deposit February 24, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Gwen Frickhoeffer CLT01/4795106v1